Registration Decision RD2016-25

Fluopyram

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Publications
Pest Management Regulatory Agency
Health Canada
2720 Riverside Drive
A.L. 6607 D
Ottawa, Ontario K1A 0K9

Internet: pmra.publications@hc-sc.gc.ca
healthcanada.gc.ca/pmra
Facsimile: 613-736-3758
Information Service:
1-800-267-6315 or 613-736-3799
pmra.infoserv@hc-sc.gc.ca

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Registration Decision Statement[1] for Fluopyram

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is granting full registration for the sale and use of Fluopyram Technical Fungicide and three end-use products, Exteris Stressgard (previously known as FLU+TFS 1:1 SC Fungicide) containing the technical grade active ingredients fluopyram and trifloxystrobin, as well as Ilevo (previously known as Fluopyram ST) and Fluopyram Greenhouse Fungicide, both containing the technical grade active ingredient fluopyram. All three end-use products are used to control several fungal diseases on turfgrass, soybean seeds or food crops.

This decision is consistent with the Proposed Registration Decision PRD2016-11, *Fluopyram*, which contains a detailed evaluation of the information submitted in support of this registration. The evaluation found that, under the approved conditions of use, the products have value and do not present an unacceptable risk to human health or the environment. See Appendix I for a summary of comments received during the consultation process as well as the PMRA's response to these comments.

Other Information

The relevant test data on which the decision is based (as referenced in PRD2016-11) are available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa). For more information, please contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail (pmra.infoserv@hc-sc.gc.ca).

[1] "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

Appendix I Comments and Responses

Comment

For the end-use product Exteris Stressgard, a comment was received from the registrant requesting the following statement on the product label: "Self-contained bodies of water within the golf course property DO NOT require buffer zones (for example, ponds with no inflow or outflow of water)".

Response

This sentence cannot be added to the product label because the PMRA considers self-contained bodies of water, including those in golf courses, to be wildlife habitats and, therefore, the buffer zone requirement also applies to these ponds.

Comment

For the end-use product Exteris Stressgard, the registrant requested that a restricted-entry interval (REI) statement be modified. The REI statement proposed by PMRA for golf course use is "until spray has dried", and for sod farm use is a 12-hour REI. A request was made to change the sod farm statement to "until spray has dried".

Response

It is not possible to change the REI statement for sod farms. The end-use product, Exteris Stressgard, is a coformulation of the active ingredients fluopyram and trifloxystrobin. Trifloxystrobin is currently registered for the control of various diseases in golf course and sod farm turf with an REI on the end-use product label of 12 hours for sod farms. As such, the same REI is required for Exteris Stressgard, containing both fluopyram and trifloxystrobin.

While golf course turf grass covers relatively limited areas such as fairways, tees and putting greens, turfgrass sod is a mature grass cover, which is produced in much larger scale, intensively managed agricultural operations. The difference in hectarage between golf course turf maintenance and sod farm turf agronomy is reflected in the default Area Treated per Day values used in conducting mixer/loader/applicator risk assessments: 16 ha for groundboom application of golf courses versus 30 ha for groundboom application of sod farms. As such, workers and the public can re-enter treated golf courses, which are non-agricultural areas, when residues have dried. However, since sod farms are intensively managed agricultural operations, workers cannot re-enter to conduct hand labour tasks in treated sod farms prior to the REI of 12 hours.

Why is the minimum REI 12 hours?

REIs protect workers, and others, from risks that may occur from both immediate and longer-term exposures to pesticide residues, vapours and particulates. A minimum 12-hour REI allows residues to dry and vapours to dissipate, limiting potential effects such as irritation or allergic reactions.

Given that sod farm cultivated turf production represents a large scale, agronomically intensive activity compared to golf course turf maintenance, and given that the trifloxystrobin component

of the Exteris Stressgard is currently registered for sod farm turf use with an REI of 12 hours, the requested revision of the REI for sod farm applications from 12 hours to "until spray has dried" on the Exteris Stressgard cannot be supported.

Comment

A comment was received from the registrant pertaining to the requirement for a closed-cab tractor when planting more than 2900 kg of fluopyram-treated soybean seed in a day. The comment indicated that the requirement for a closed-cab tractor when planting more than 2900 kg of fluopyram-treated soybean in a day should be waived. This was based on rationales stating that soybean seeds have less dust-off than some other treated seeds (for example, corn), on the majority of exposure happening during loading and not while planting, and also that the PMRA exposure risk assessment is too conservative and the actual exposure is less than calculated by the PMRA.

Response

The PMRA appreciates the registrant bringing forth the points above to justify their stance that a closed-cab tractor requirement is not required. However, the PMRA has considered these points, as well as other data and information from the registrant and government resources collectively, and concludes that the closed-cab tractor requirement proposed in PRD2016-11 cannot be waived for the following reasons:

a) In the risk assessment submitted by the registrant, 5074 kg seed planted per day was assumed. The registrant used the average Canadian soybean farm size of 59 ha to calculate this value. However, the PMRA must also consider larger soybean farms for risk assessment purposes.

   The PMRA assumed an area planted per day of 80 ha/day for soybeans based on planting equipment from the United States Environmental Protection Agency Standard Operating Procedure #15, even though the 95th percentile of Canadian soybean farm sizes is 202 ha in the 2011 Census of Agriculture. Using the maximum soybean seeding rate recommended by the Ontario Ministry of Agriculture, Food and Rural Affairs (109 kg/ha), the amount of soybean seed planted per day is approximately 9000 kg/day. This was the value used in the planting risk assessment published in PRD2016-11. As such, there will be no revisions to Table 3.4.2.2.2 in PRD2016-11.

b) The PMRA believes that an enclosed cab significantly mitigates exposure from planting treated seed, as observed in passive dosimetry studies for other scenarios. Only exposure data from closed-cab planting are available, and thus, were used to assess risk from planting Ilevo-treated soybean seed. As such, planting of treated seed must be conducted in a closed-cab, unless calculated margins of exposure (MOEs) are well above the target MOE.

   Margins of exposure must be well above the target MOE since it is uncertain to what extent closed cabs mitigate exposure from planting treated seed. The registrant has stated that the requirement for an enclosed cab would not affect the exposure during the loading process, since the surrogate study report described

that the majority of exposure is likely to have occurred during the loading phase and primarily to the hands. However, further evaluation of the surrogate data indicated that all gloved-workers that were monitored had higher hand exposure in the sowing phase compared to the loading/unloading phase. In addition, the comparison of open and enclosed cab unit exposures from other exposure scenarios, such as groundboom applications, cannot be used quantitatively.

Although dust-off data bridging the proposed use and the surrogate study provides insight as to whether the risk assessment will underestimate or overestimate risk, it cannot be used quantitatively when considering the difference between the calculated MOE and target MOE. This is due to the variability seen in dust-off data. For example, the dust-off potential in corn was 9.6 times higher than that for soybean in the study cited in the registrant's comment, but was 4.6 times higher in the dust-off study submitted for fluopyram.

The registrant has cited the risk assessment of prothioconazole in PRD2011-07 as a precedent for waiving the closed-cab requirement. However, since the publication of PRD2011-07, the PMRA has gained experience and knowledge in the field of seed treatment. Consequently, the criteria in regards to waiving closed-cab planting of treated seed have evolved. As such, for Ilevo, calculated MOEs were well above the target MOE of 100 when workers plant 2900 kg of treated seed or less per day. However, with planting more treated seed in open-cab tractors, there is more uncertainty as to whether health risks are not of concern. Therefore, when planting more than 2900 kg of fluopyram-treated soybean seed per day, workers must plant using closed-cab tractors.